

DEC 04 2002

K023871
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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

David Osborn
Philips Medical Systems
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This summary was prepared on November 18, 2002

2. The names of the devices are the M3046A (M2/M3/M4) Compact Portable Patient Monitor and MP60 & MP70 IntelliVue Patient Monitors with Portal Technology. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Circulatory System Devices (12625)	§870.1025, III	DSI	Detector and alarm, arrhythmia
	§870.1025, III	MLD	Monitor, ST Segment with Alarm
	§870.1025, III	MHX	Monotor, Physiological, Patient (with arrhythmia detection or alarms)
	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood- Pressure, Non-Invasive
	§870.1435, II	DXG	Computer, Diagnostic, Pre- Programmed, Single-Function
	§870.1915, II	KRB	Probe, Thermodilution
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment
	§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	§870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	§870.2450, II	DXJ	Display, Cathode-Ray Tube, Medical
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2700, II	DQA	Oximeter
	§870.2770, II	DSB	Plethysmograph, Impedance
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
	§870.2810, I	DSF	Recorder, Paper Chart

	\$870.2850, II	DRS	Extravascular Blood Pressure Transducer
	\$870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors
Anesthesiology and Respiratory Therapy (12624)	\$868.1400, II	CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
	\$868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1700, II	CBR	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase (Anesthetic Concentration)
	\$868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	\$868.2375, II	BZQ	Monitor, Breathing Frequency
	\$868.2480, II	LKD	Monitor, Carbon Dioxide, Cutaneous
	\$868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
General Hospital and Personal Use (12520)	\$880.2910, II	FLL	Thermometer, Electronic, Clinical
Neurological (12513)	\$882.1400, II	GWR	Electroencephalograph
	\$882.1420, I	GWS	Analyzer, Spectrum, Electroencephalogram Signal

3. The new devices are substantially equivalent to previously cleared Philips devices marketed pursuant to K013427 and K021778.
4. The modification is primarily a software-based change that incorporates a Data Export function communication protocol to transfer data from the patient monitors to an external computer or external device (a data client). This protocol is a connection oriented, message based request/response protocol.
5. The new devices have the same intended use as the legally marketed predicate devices. When used in the hospital environment and/or in medical transport, they are intended for the monitoring, recording,

and alarming of multiple physiological parameters of adults, pediatrics, and neonates.

6. The new devices have the same technological characteristics as the legally marketed predicate devices.
7. Verification testing activities were conducted to establish the performance and reliability characteristics of the new device. Testing involved functional level tests and safety testing from the risk analysis.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 04 2002

Philips Medical Systems
c/o Mr. Dave Osborn
Quality Program Manager
Cardiac and Monitoring Systems
3000 Minuteman Road
Andover, MA 01810

Re: K023871

Trade Name: M3046A (M2/M3/M4) Compact Portable Patient Monitor and MP60 & MP70
IntelliVue Patient Monitors with Portal Technology

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia Detector and Alarm

Regulatory Class: Class III (three)

Product Code: MHX

Dated: November 19, 2002

Received: November 20, 2002

Dear Mr. Osborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

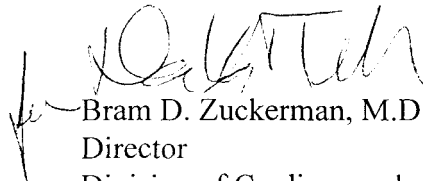
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K023871

Device Name: The M3046A (M2/M3/M4) Compact Portable Patient Monitor and MP60 & MP70 IntelliVue Patient Monitors with Portal Technology

Indications for Use (M3046A): For monitoring, recording and alarming of multiple physiological parameters of adults, pediatrics and neonates in hospital and/or medical transport environments.

Indications for Use (MP60 & MP70): Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters patients. Intended for monitoring, recording and alarming of multiple physiological parameters of adults, pediatrics and neonates in health care facilities.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
21 CFR 801.109)

OR

Over-The-Counter (Per

(Optional Format 1-2-96)

K023871
(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K023871